



2023/0132(COD)

03.10.2023

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DRAFT REPORT

on the proposal for a directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC

(COM(2023)0192 – C9-0143/2023 – 2023/0132(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Pernille Weiss

Symbols for procedures

- * Consultation procedure
- *** Consent procedure
- ***I Ordinary legislative procedure (first reading)
- ***II Ordinary legislative procedure (second reading)
- ***III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the **■** symbol or ~~strikeout~~. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.

By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC

(COM(2023)0192 – C9-0143/2023 – 2023/0132(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2023)0192),
 - having regard to Article 294(2) and Article 114(1) and Article 168(4), point (c), of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0143/2023),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of ...¹,
 - having regard to the opinion of the Committee of the Regions of ...²,
 - having regard to Rule 59 of its Rules of Procedure,
 - having regard to the opinion of the Committee on Industry, Research and Energy,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety (A9-0000/2023),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

¹ OJ C 0, 0.0.0000, p. 0. / Not yet published in the Official Journal.

² OJ C 0, 0.0.0000, p. 0. / Not yet published in the Official Journal.

Amendment 1

Proposal for a directive Recital 3

Text proposed by the Commission

(3) This revision is part of the implementation of the Pharmaceutical strategy for Europe and aims to promote innovation, in particular for unmet medical needs, while reducing regulatory burden and the environmental impact of medicines; ensure access to innovative and established medicines for patients, with special attention to enhancing security of supply and addressing risks of shortages, taking into account the challenges of the smaller markets of the Union; and create a balanced and competitive system that keeps medicines affordable for health systems while rewarding innovation.

Amendment

(3) This revision is part of the implementation of the Pharmaceutical strategy for Europe and aims to promote innovation, in particular for unmet medical needs, ***and create an attractive environment for research, development and production of medicines in the Union*** while reducing regulatory burden and the environmental impact of medicines; ensure access to innovative and established medicines for patients, with special attention to enhancing security of supply and addressing risks of shortages, taking into account the challenges of the smaller markets of the Union; and create a balanced and competitive system that keeps medicines affordable for health systems while rewarding innovation.

Or. en

Amendment 2

Proposal for a directive Recital 11 a (new)

Text proposed by the Commission

Amendment

(11a) This Directive should be consistent with the Union's objectives with regard to promotion of research, innovation and industrial competitiveness, including with regard to a globally competitive system of intellectual property (IP) incentives. The provisions of this Directive should be coordinated with the Union's industrial and digital strategies as well as its trade policy to ensure that the Union is capable

of competing with challenger regions, as highlighted by the resolution of the European Parliament of 24 November 2021 on a pharmaceutical strategy for Europe^{1a}. Likewise, the conclusions of the Council of 23 March 2023 on competitiveness, single market and the economy have stressed the importance of strengthening incentives for investments in innovation. In that regard, it should be considered how the European life science sector, including the pharmaceutical industry, contributes as a whole to meeting those objectives and thus how this Directive should work to support it.

^{1a} OJ C 224, 8.6.2022, p. 47.

Or. en

Amendment 3

Proposal for a directive

Recital 18

Text proposed by the Commission

(18) Advanced therapy medicinal products that are prepared on a non-routine basis according to specific quality standards, and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient, should be excluded from the scope of this Directive whilst at the same time ensuring that relevant Union rules related to quality and safety are not undermined ('hospital exemption'). Experience has shown that there are great differences in the application of hospital exemption among Member States. To improve the application of hospital exemption this Directive introduces measures for

Amendment

(18) Advanced therapy medicinal products that are prepared on a non-routine basis according to specific quality standards, and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient, should be excluded from the scope of this Directive whilst at the same time ensuring that relevant Union rules related to quality and safety are not undermined ('hospital exemption'). Experience has shown that there are great differences in the application of hospital exemption among Member States. To improve the application of hospital exemption this Directive introduces measures for

collection, reporting of data as well as review of these data yearly by the competent authorities and their publication by the Agency in a repository. Furthermore, the Agency should provide a report on the implementation of hospital exemption on the basis of contributions from Member States ***in order to examine whether an adapted framework should be established for certain less complex ATMPs that have been developed and used under the hospital exemption.*** When an authorisation for the manufacturing and use of an ATMP under hospital exemption is revoked because of safety concerns, the relevant competent authorities shall inform the competent authorities of other Member States.

collection, reporting of data as well as review of these data yearly by the competent authorities and their publication by the Agency in a repository. Furthermore, the Agency should provide a report on the implementation of hospital exemption on the basis of contributions from Member States. When an authorisation for the manufacturing and use of an ATMP under hospital exemption is revoked because of safety concerns, the relevant competent authorities shall inform the competent authorities of other Member States.

Or. en

Amendment 4

Proposal for a directive Recital 18 a (new)

Text proposed by the Commission

Amendment

(18a) The Agency should establish a programme with the objective to guide academic and other not-for-profit entities through the centralised marketing authorisation procedure. That programme should be able to draw on results of the European Medicines Agency (EMA) pilot programme for enhanced support to academic and non-profit developers of advanced therapy medicinal products, started in September 2022.

Or. en

Amendment 5

Proposal for a directive Recital 19

Text proposed by the Commission

(19) This Directive should be without prejudice to the provisions of Council Directive 2013/59/Euratom⁴¹, ***including with respect to justification and optimisation of protection of patients and other individuals subject to medical exposure to ionising radiation. In the case of radiopharmaceuticals used for therapy, marketing authorisations, posology and administration rules have to notably respect that Directive's requirements that exposures of target volumes are to be individually planned, and their delivery appropriately verified taking into account that doses to non-target volumes and tissues are to be as low as reasonably achievable and consistent with the intended therapeutic purpose of the exposure.***

⁴¹ Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17.1.2014, p. 1).

Amendment

(19) This Directive should be without prejudice to the provisions of Council Directive 2013/59/Euratom⁴¹.

⁴¹ Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17.1.2014, p. 1).

Or. en

Amendment 6

Proposal for a directive Recital 26

Text proposed by the Commission

(26) In order to reward the compliance

Amendment

(26) In order to reward the compliance

with all the measures included in the agreed paediatric investigation plan, for products covered by a supplementary protection certificate, if relevant information on the results of the studies conducted is included in the product information, a reward should be granted in the form of **a six month** extension of the supplementary protection certificate created by [Regulation (EC) No 469/2009 of the European Parliament and of the Council⁴² - OP please replace reference by new instrument when adopted].

⁴² Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152, 16.6.2009, p. 10).

with all the measures included in the agreed paediatric investigation plan, for products covered by a supplementary protection certificate, if relevant information on the results of the studies conducted is included in the product information, a reward should be granted in the form of **an** extension of the supplementary protection certificate created by [Regulation (EC) No 469/2009 of the European Parliament and of the Council⁴² - OP please replace reference by new instrument when adopted].

⁴² Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152, 16.6.2009, p. 10).

Or. en

Justification

See amendment to Article 86 – paragraph 1 – subparagraph 1.

Amendment 7

Proposal for a directive Recital 46 a (new)

Text proposed by the Commission

Amendment

(46a) Member States apply diverse procedures and measures in the pricing and reimbursement of medicinal products. Those procedures and measures significantly affect access to medicinal products, especially with regard to the speed at which access is achieved. Likewise, Member States apply specific procedures and measures pertaining to the promotion of competition from generic and biosimilar medicinal products. Having regard to the competence of the Member States, and

recognising the disparities which can be observed in access to medicines across the Union, the exchange of best practice among national competent authorities in that area should be given greater priority. In that regard, the Commission should play a distinct role in facilitating the exchange of best practices.

Or. en

Amendment 8

Proposal for a directive

Recital 47

Text proposed by the Commission

(47) To ensure dialogue among all actors in the medicines lifecycle, discussions on policy issues related to the application of the rules related to prolongation of regulatory data protection **for market launch** shall take place in the Pharmaceutical Committee. The Commission may invite bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 or national bodies responsible for pricing and reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.

Amendment

(47) To ensure dialogue among all actors in the medicines lifecycle, discussions on policy issues related to the application of the rules related to prolongation of regulatory data protection shall take place in the Pharmaceutical Committee. The Commission may invite bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 or national bodies responsible for pricing and reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.

Or. en

Amendment 9

Proposal for a directive

Recital 49

Text proposed by the Commission

(49) **Joint procurement, whether within a country or across countries, can improve access, affordability, and security**

Amendment

(49) Member States interested in joint procurement of medicines can make use of Directive 2014/24/EU⁴⁷, which sets out

of supply of medicines, in particular for smaller countries. Member States interested in joint procurement of medicines can make use of Directive 2014/24/EU⁴⁷, which sets out purchasing procedures for public buyers, the Joint Procurement Agreement⁴⁸ and the proposed revised Financial Regulation⁴⁹. ***Upon request from the Member States the Commission may support interested Member States by facilitating coordination to enable access to medicines for patients in the Union as well as information exchange, in particular for medicines for rare and chronic diseases.***

⁴⁷ Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65).

⁴⁸ Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU.

⁴⁹ COM/2022/223 final.

purchasing procedures for public buyers, the Joint Procurement Agreement⁴⁸ and the proposed revised Financial Regulation⁴⁹. In the ***event of joint procurement of medicinal products as a medical countermeasure in cases of serious cross-border threats to health, the provisions of Regulation (EU) 2022/2371 of the European Parliament and of the Council^{49a} apply.***

⁴⁷ Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65).

⁴⁸ Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU.

⁴⁹ COM/2022/223 final.

^{49a} Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26).

Or. en

Amendment 10

Proposal for a directive Recital 50

Text proposed by the Commission

(50) The establishment of a criteria-based definition of ‘unmet medical need’ is

Amendment

(50) The establishment of a criteria-based definition of ‘unmet medical need’ is

required to incentivise the development of medicinal products in therapeutic areas that are currently underserved. To ensure that the concept of unmet medical need reflects scientific and technological developments and current knowledge in underserved diseases, the Commission should specify and update using implementing acts, the criteria of satisfactory method of diagnosis, prevention or treatment, ‘remaining high morbidity or mortality’, ‘relevant patient population’ following scientific assessment by the Agency. The Agency will seek input from a broad range of authorities or bodies active along the lifecycle of medicinal products in the framework of the consultation process established under the [revised Regulation (EC) No 726/2004] and also take into account scientific initiatives at EU level or between Member States related to analysing unmet medical needs, burden of disease and priority setting for research and development. The criteria for ‘unmet medical need’ can be subsequently used by Member States to identify specific therapeutic areas of interest.

required to incentivise the development of medicinal products in therapeutic areas that are currently underserved. To ensure that the concept of unmet medical need reflects scientific and technological developments and current knowledge in underserved diseases, the Commission should specify and update using implementing acts, the criteria of satisfactory method of diagnosis, prevention or treatment, ‘remaining high morbidity or mortality’, ***‘quality of life’***, ‘relevant patient population’ following scientific assessment by the Agency. The Agency will seek input from a broad range of authorities or bodies active along the lifecycle of medicinal products in the framework of the consultation process established under the [revised Regulation (EC) No 726/2004] and also take into account scientific initiatives at EU level or between Member States related to analysing unmet medical needs, burden of disease and priority setting for research and development. The ***Agency should also seek input from other relevant stakeholders.*** The criteria for ‘unmet medical need’ can be subsequently used by Member States to identify specific therapeutic areas of interest.

Or. en

Justification

See amendment to Article 83.

Amendment 11

Proposal for a directive Recital 50 a (new)

Text proposed by the Commission

Amendment

(50a) The development of medical products in underserved therapeutic areas can greatly increase the quality of life for patients. In that regard, elements such as

acute or chronic side effects, in particular in relation to the toxicity of a product, as well as the ability of patients to perform regular life activities, the presence of pain and the management of co-morbidities should be considered in the assessment of improving quality of life. Improving quality of life can allow patients to return to job or education, which can not only bear a significant positive effect on the individual patient, but can also alleviate costs to society arising from productivity losses. Furthermore, novel medicinal products which have significant positive impacts on the quality of life of a patient can also alleviate the burden on family and carers, in particular as regards paediatric patients. This will in turn also have a societal impact in areas such as labour shortages and fiscal budgets.

Or. en

Justification

See amendments to Article 83.

Amendment 12

Proposal for a directive Recital 52

Text proposed by the Commission

(52) For the *initial* marketing authorisation application for medicinal products containing a new active substance, the submission of clinical trials that include as a comparator an evidence-based existing treatment should be incentivised, in order to foster the generation of comparative clinical evidence that is relevant and can accordingly support subsequent health technology assessments and decisions on pricing and reimbursement by Member States.

Amendment

(52) For the marketing authorisation application for medicinal products containing a new active substance, the submission of clinical trials that include as a comparator an evidence-based existing treatment should be incentivised, in order to foster the generation of comparative clinical evidence that is relevant and can accordingly support subsequent health technology assessments and decisions on pricing and reimbursement by Member States.

Amendment 13

Proposal for a directive Recital 53

Text proposed by the Commission

(53) A marketing authorisation holder should ensure the appropriate and continuous supply of a medicinal product throughout its lifetime ***irrespective of whether that medicinal product is covered by a supply incentive or not.***

Amendment

(53) A marketing authorisation holder should, ***within its responsibilities,*** ensure the appropriate and continuous supply of a medicinal product throughout its lifetime.

Or. en

Justification

See amendment to Article 81.

Amendment 14

Proposal for a directive Recital 54

Text proposed by the Commission

(54) Micro, small and medium-sized enterprises ('SMEs'), not-for-profit entities or entities with limited experience in the Union system should benefit from additional time to ***market*** a medicinal product in the Member States where the marketing authorisation is valid ***for the purposes of receiving additional regulatory data protection.***

Amendment

(54) Micro, small and medium-sized enterprises ('SMEs'), not-for-profit entities or entities with limited experience in the Union system should benefit from additional time to ***submit an application for pricing and reimbursement for*** a medicinal product in the Member States where the marketing authorisation is valid, ***and where a Member State has requested it.***

Or. en

Justification

See amendments to new Article 58a.

Amendment 15

Proposal for a directive Recital 55

Text proposed by the Commission

(55) ***When applying the provisions on market launch incentives***, marketing authorisation holders and Member States should do their utmost to achieve a mutually agreed supply of medicinal products in accordance with the needs of the Member State concerned, without unduly delaying or hindering the other party from enjoying its rights under this Directive.

Amendment

(55) Marketing authorisation holders and Member States should do their utmost to achieve a mutually agreed supply of medicinal products in accordance with the needs of the Member State concerned, without unduly delaying or hindering the other party from enjoying its rights under this Directive.

Or. en

Justification

See amendments to new Article 58a.

Amendment 16

Proposal for a directive Recital 56

Text proposed by the Commission

(56) ***Member States have the possibility to waive the condition of launch in their territory for the purpose of the prolongation of data protection for market launch. This can be done through a statement of non-objection to prolong the period of regulatory data protection. This is expected to be the case particularly in situations where launch in a particular Member State is materially impossible or because there are special reasons why a Member State wishes that launch take place later.***

Amendment

deleted

Justification

See amendments to new Article 58a.

Amendment 17**Proposal for a directive
Recital 58***Text proposed by the Commission*

(58) An alternative way of demonstrating supply relates to the inclusion of medicinal products in a positive list of medicinal products covered by the national health insurance system in accordance with Directive 89/105/EEC. The related negotiations between companies and the Member State should be conducted in good faith.

Amendment

(58) An alternative way of demonstrating supply relates to the inclusion of medicinal products in a positive list of medicinal products covered by the national health insurance system in accordance with Directive 89/105/EEC. The related negotiations between companies and the Member State should be conducted in good faith. ***Equally, to promote faster and wider access to medicines, it is critical that the timelines set out in that Directive are respected in negotiations between applicants and Member States, and that negotiations are conducted in good faith.***

Or. en

Amendment 18**Proposal for a directive
Recital 58 a (new)***Text proposed by the Commission**Amendment*

(58a) Cross-border healthcare is an important pathway for patients to access medicinal products that might otherwise not be available to them. To support access to medicinal products, in particular in the case of small patient populations or where the administration of a medicine requires special competences or

infrastructure, the full implementation of Directive 2011/24/EU of the European Parliament and of the Council^{1a} should be supported. It is important to consider in that regard all alternative paths of making available medicinal products to patients and prescribing doctors, such as named patient supply, administering of medicine via a centre of excellence, early access or compassionate use programs, and other cross-border healthcare. Competent authorities of the Member States should therefore utilise the NCAPR to exchange and share best practice regarding the implementation of cross-border access agreements and negotiations.

^{1a} Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

Or. en

Amendment 19

Proposal for a directive Recital 59

Text proposed by the Commission

Amendment

(59) A Member State that considers that the conditions of supply have not been met for its territory should provide a reasoned statement of non-compliance at the latest in the Standing Committee on Medicinal Products for Human Use procedure of the variation linked to the provision of the relevant incentive.

deleted

Or. en

Justification

See amendments to new Article 81.

Amendment 20

Proposal for a directive Recital 61

Text proposed by the Commission

(61) When a compulsory licence has been granted by a relevant authority in the Union to tackle a public health emergency, regulatory data protection may, if still in force, prevent the effective use of the compulsory licence as they impede the authorisation of generic medicinal products, and thus access to the medicinal products needed to address the crisis. For this reason, data and market protection should be suspended when a compulsory licence has been issued to tackle a public health emergency. Such a suspension of the regulatory data protection should be allowed only in relation to the compulsory licence granted and its beneficiary. The suspension shall comply with the objective, the territorial scope, the duration and the subject matter of the granted compulsory licence.

Amendment

(61) When a compulsory licence has been granted by a relevant authority in the Union to tackle a public health emergency, regulatory data protection may, if still in force, prevent the effective use of the compulsory licence as they impede the authorisation of generic medicinal products, and thus access to the medicinal products needed to address the crisis. For this reason, data and market protection should be suspended ***for the indication that is relevant to the public health emergency*** when a compulsory licence has been issued to tackle a public health emergency. Such a suspension of the regulatory data protection should be allowed only in relation to the compulsory licence granted and its beneficiary. The suspension shall comply with the objective, the territorial scope, the duration and the subject matter of the granted compulsory licence.

Or. en

Amendment 21

Proposal for a directive Recital 62

Text proposed by the Commission

(62) The suspension of the regulatory data protection should be granted only for the duration of the compulsory licence. A ‘suspension’ of data and market protection in cases of public health emergency shall mean that data and market protection shall

Amendment

(62) The suspension of the regulatory data protection should be granted only for the duration of the compulsory licence ***and only in the relevant Member States***. A ‘suspension’ of data and market protection in cases of public health emergency shall

produce no effect in relation to the particular licensee of the compulsory licence while that compulsory licence is in effect. When the compulsory licence ends, the data and market protection shall resume their effect. The suspension should not result in an extension of the original duration.

mean that data and market protection shall produce no effect in relation to the particular licensee of the compulsory licence while that compulsory licence is in effect. When the compulsory licence ends, the data and market protection shall resume their effect. The suspension should not result in an extension of the original duration.

Or. en

Amendment 22

Proposal for a directive

Recital 63

Text proposed by the Commission

(63) It is currently possible for applicants for marketing authorisation of generic, biosimilar, hybrid and bio-hybrid medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain regulatory approvals for those medicinal products during the term of protection of the patent or Supplementary Protection Certificate (SPC) of the reference medicinal product, without this being considered patent or SPC infringement. The application of this limited exemption is however fragmented across the Union and it is considered necessary, in order to facilitate the market entry of generic, biosimilar, hybrid and bio-hybrid medicinal products that rely on a reference medicinal product, to clarify its scope in order to ensure a harmonised application in all Member States, both in terms of beneficiaries and in terms of activities covered. The exemption must be confined to conduct studies and trials and other activities needed for the regulatory approval process, health technology assessment **and pricing reimbursement request, even though this may require**

Amendment

(63) It is currently possible for applicants for marketing authorisation of generic, biosimilar, hybrid and bio-hybrid medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain regulatory approvals for those medicinal products during the term of protection of the patent or Supplementary Protection Certificate (SPC) of the reference medicinal product, without this being considered patent or SPC infringement. The application of this limited exemption is however fragmented across the Union and it is considered necessary, in order to facilitate the market entry of generic, biosimilar, hybrid and bio-hybrid medicinal products that rely on a reference medicinal product, to clarify its scope in order to ensure a harmonised application in all Member States, both in terms of beneficiaries and in terms of activities covered. The exemption must be confined to conduct studies and trials and other activities needed for the regulatory approval process, **and** health technology assessment. During the term of protection of the patent or SPC of the reference

substantial amounts of test production to demonstrate reliable manufacturing.

During the term of protection of the patent or SPC of the reference medicinal product, there can be no commercial use of the resulting final medicinal products obtained for the purposes of the regulatory approval process.

medicinal product, there can be no commercial use of the resulting final medicinal products obtained for the purposes of the regulatory approval process.

Or. en

Amendment 23

Proposal for a directive

Recital 64

Text proposed by the Commission

(64) It will allow, inter alia, ***to conduct studies to support pricing and reimbursement as well as*** the manufacture or purchase of patent protected active substances for the purpose of seeking marketing authorisations during that period, contributing to the market entry of generics and biosimilars on day one of loss of the patent or SPC protection.

Amendment

(64) It will allow, inter alia, the manufacture or purchase of patent protected active substances for the purpose of seeking marketing authorisations during that period, contributing to the market entry of generics and biosimilars on day one of loss of the patent or SPC protection.

Or. en

Amendment 24

Proposal for a directive

Recital 70

Text proposed by the Commission

(70) Marketing authorisation applications for medicinal products in the Union should include an Environmental Risk Assessment (ERA) and risk mitigation measures. If the applicant fails to submit a complete or sufficiently substantiated environmental risk assessment or they do not propose risk

Amendment

(70) Marketing authorisation applications for medicinal products in the Union should include an Environmental Risk Assessment (ERA) and risk mitigation measures. If the applicant fails to submit a complete or sufficiently substantiated environmental risk assessment or they do not propose risk

mitigation measures to sufficiently address the risks identified in the environmental risk assessment, the marketing authorisation ***should be refused***. The ERA should be updated when new data or knowledge about relevant risks become available.

mitigation measures to sufficiently address the risks identified in the environmental risk assessment, ***it should be possible to refuse*** the marketing authorisation. The ERA should be updated when new data or knowledge about relevant risks become available.

Or. en

Amendment 25

Proposal for a directive Recital 72

Text proposed by the Commission

(72) The emissions and discharges of antimicrobials to the environment from manufacturing sites may lead to antimicrobial resistance (“AMR”), which is a global concern regardless where the emissions and discharges take place. Therefore, the ERA scope should be extended to cover the risk of AMR selection during the entire life cycle of antimicrobials, including manufacturing.

Amendment

(72) The emissions and discharges of antimicrobials to the environment from manufacturing sites may lead to antimicrobial resistance (“AMR”), which is a global concern regardless where the emissions and discharges take place. Therefore, the ERA scope should be extended to cover the risk of AMR selection during the entire life cycle of antimicrobials, including manufacturing. ***At the date of adoption of this Directive, there is not a scientifically agreed method to set regulatory values for the contribution of manufacturing to antimicrobial resistance other than for antibiotic resistance. The Commission should therefore issue guidelines on how to conduct ERAs for AMR selection for microbials other than bacteria after consulting the EMA, the European Centre for Disease Prevention and Control (ECDC) and the European Environment Agency.***

Or. en

Amendment 26

Proposal for a directive Recital 93

Text proposed by the Commission

(93) To optimise the use of resources for both applicants for marketing authorisation and competent authorities and avoid duplication of assessment of chemical active substances of medicinal products, marketing authorisation applicants should be able to rely on an active substance master file certificate or a monograph of the European Pharmacopeia, instead of submitting the relevant data as required in accordance with Annex II. An active substance master file certificate may be granted by the Agency when the relevant data on the active substance concerned is not already covered by a monograph of the European Pharmacopeia or by another active substance master file certificate. The Commission should be empowered to establish the procedure for the single assessment of an active substance master file. To further optimise the use of resources, the Commission should be empowered to allow use a certification scheme also for additional quality master files i.e. for active substances other than chemical active substances, or for other substances present or used in the manufacture of a medicinal product, required in accordance with Annex II, e.g. in case of novel excipients, adjuvants, radiopharmaceutical precursors and active substance intermediates, when the intermediate is a chemical active substance by itself or used in conjugation with a biological substance.

Amendment

(93) To optimise the use of resources for both applicants for marketing authorisation and competent authorities and avoid duplication of assessment of chemical active substances of medicinal products **and cell and gene therapies**, marketing authorisation applicants should be able to rely on an active substance master file certificate or a monograph of the European Pharmacopeia, instead of submitting the relevant data as required in accordance with Annex II. An active substance master file certificate may be granted by the Agency when the relevant data on the active substance concerned is not already covered by a monograph of the European Pharmacopeia or by another active substance master file certificate. The Commission should be empowered to establish the procedure for the single assessment of an active substance master file. To further optimise the use of resources, the Commission should be empowered to allow use **of** a certification scheme also for additional **master files, including** quality master files, i.e. for active substances other than chemical active substances, or for other substances present or used in the manufacture of a medicinal product, required in accordance with Annex II, e.g. in case of novel excipients, adjuvants, radiopharmaceutical precursors and active substance intermediates, when the intermediate is a chemical active substance by itself or used in conjugation with a biological substance, **as well as for raw materials and starting materials used for manufacturing of cell therapy and gene therapy.**

Or. en

Justification

See amendment to new Article 26a.

Amendment 27

Proposal for a directive

Recital 124

Text proposed by the Commission

(124) Rules should be laid down as to how the labelling and package leaflets are to be presented.

Amendment

(124) Rules should be laid down as to how the labelling and package leaflets are to be presented. ***The package leaflet should be easily legible, clearly comprehensible and indelible by users, including especially the target patient groups. Patient leaflets are in the category of consultative reading which means that relevant information should be found without reading the whole leaflet. For readability and legibility, the package leaflet can benefit from a typographic hierarchy and a legible typeface. Design choices should serve function and readability, rather than aesthetics, and secondarily consider the environmental sustainability of the leaflet.***

Or. en

Amendment 28

Proposal for a directive

Recital 131

Text proposed by the Commission

(131) To ensure a high level of transparency of public support to the research and development of medicinal products, the reporting of public contribution for the development of a particular medicinal product should be a requirement for all medicines. Given however the practical difficulty to identify

Amendment

(131) To ensure a high level of transparency of public support to the research and development of medicinal products, the reporting of public contribution for the development of a particular medicinal product should be a requirement for all medicines. Given however the practical difficulty to identify

how indirect public funding instruments, such as tax advantages, have supported a particular product, the reporting obligation should only concern the direct public financial support, such as direct grants or contracts. Therefore, the provisions of this Directive ensure, without prejudice to the rules on the protection of confidential and personal data, transparency regarding any direct financial support received from any public authority or public body to carry out any activities for the research and development of medicinal products.

how indirect public funding instruments, such as tax advantages, have supported a particular product, the reporting obligation should only concern the direct public financial support, such as direct grants or contracts. Therefore, the provisions of this Directive ensure, without prejudice to the rules on the protection of confidential and personal data, transparency regarding any direct financial support received from any public authority or public body *of the Union* to carry out any activities for the research and development of medicinal products.

Or. en

Amendment 29

Proposal for a directive Recital 149

Text proposed by the Commission

(149) In order to supplement or amend certain non-essential elements of this Directive, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of specifying the procedure for examination of application of active substance master file certificate, the publication of such certificates, the procedure for changes to the active substance master file and its certificate, access to the active substance master file and its assessment report; specifying additional *quality* master files to provide information on a constituent of a medicinal product, the procedure for examination of application of a quality master file certificate, the publication of such certificates, the procedure for changes to the *quality* master file and its certificate, and access to the *quality* master file and its assessment report; determining the situations in which post-authorisation

Amendment

(149) In order to supplement or amend certain non-essential elements of this Directive, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of specifying the procedure for examination of application of active substance master file certificate, the publication of such certificates, the procedure for changes to the active substance master file and its certificate, access to the active substance master file and its assessment report; specifying additional master files to provide information on a constituent of a medicinal product, the procedure for examination of application of a quality master file certificate *or a platform technology master file certificate*, the publication of such certificates, the procedure for changes to the master file and its certificate, and access to the master file and its assessment report; determining the situations in which

efficacy studies may be required; specifying the categories of medicinal products to which a marketing authorisation subject to specific obligations could be granted and specifying the procedures and requirements for granting such a marketing authorisation and for its renewal; specifying exemptions to variation and the categories in which variations should be classified and establishing procedures for the examination of applications for variations to the terms of marketing authorisations as well as specifying conditions and procedures for cooperation with third countries and international organisations for examination of applications for such variations. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making⁶⁷. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

⁶⁷ OJ L 123, 12.5.2016, p. 1.

post-authorisation efficacy studies may be required; specifying the categories of medicinal products to which a marketing authorisation subject to specific obligations could be granted and specifying the procedures and requirements for granting such a marketing authorisation and for its renewal; specifying exemptions to variation and the categories in which variations should be classified and establishing procedures for the examination of applications for variations to the terms of marketing authorisations as well as specifying conditions and procedures for cooperation with third countries and international organisations for examination of applications for such variations. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making⁶⁷. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

⁶⁷ OJ L 123, 12.5.2016, p. 1.

Or. en

Justification

See amendment to new Article 26a.

Amendment 30

Proposal for a directive Article 2 – paragraph 1 a (new)

1a. *For the purpose of this Article, ‘non-routine basis’ means an advanced therapy medicinal product prepared under hospital exemption on an incidental and exceptional basis to meet the special needs of an individual patient, where there is neither a centrally authorised medicinal product available, nor an ongoing relevant clinical trial or compassionate use programme for the same indication with an advanced therapy medicinal product for which the patient is eligible in the Union. The following measures shall be an indication that an activity occurs on a routine basis:*

(a) the manufacturing of a product using standardised or repetitive processes; or

(b) the use of processes that involve planning in advance, beyond what is needed to address the immediate clinical needs of individual patients.

Or. en

Amendment 31

Proposal for a directive

Article 2 – paragraph 2 – subparagraph 1

Text proposed by the Commission

The manufacturing of an advanced therapy medicinal product prepared under hospital exemption shall require an approval by the competent authority of the Member State (‘hospital exemption approval’). Member States shall notify any such approval, as well as subsequent changes, to the Agency.

Amendment

The manufacturing of an advanced therapy medicinal product prepared under hospital exemption shall require an approval by the competent authority of the Member State (‘hospital exemption approval’). Member States shall notify any such approval, as well as subsequent changes, to the Agency ***which shall publish such approval in the repository referred to in paragraph 6. The hospital exemption approval shall be valid for a period of 12 months.***

Amendment 32**Proposal for a directive****Article 2 – paragraph 2 – subparagraph 2***Text proposed by the Commission*

The application for a hospital exemption approval shall be submitted to the competent authority of the Member State where the hospital is located.

Amendment

The application for a hospital exemption approval shall be submitted to the competent authority of the Member State where the hospital is located. ***The application shall include evidence on quality, safety and efficacy of the advanced therapy medicinal products prepared under hospital exemption. Before a hospital exemption approval is granted, the competent authority of the Member State shall confirm that no advanced therapy medicinal product is authorised within the Union for the same therapeutic indication, and that the manufacturing of such medicinal product complies with the requirements for preparation on a non-routine basis as set out in paragraph 1.***

Amendment 33**Proposal for a directive****Article 2 – paragraph 4***Text proposed by the Commission*

4. Member States shall ensure that data on the use, safety and the efficacy of advanced therapy medicinal products prepared under hospital exemption is collected and reported by the hospital exemption approval holder to the competent authority of the Member State at least annually. The competent authority of

Amendment

4. Member States shall ensure that data on the use, ***quality***, safety and the efficacy of advanced therapy medicinal products prepared under hospital exemption, ***as well as any relevant data from patient follow-up***, is collected and reported by the hospital exemption approval holder to the competent authority

the Member State shall review such data and shall verify the compliance of advanced therapy medicinal products prepared under hospital exemption with the requirements referred to in paragraph 3.

of the Member State at least annually. The competent authority of the Member State shall review such data and shall verify the compliance of advanced therapy medicinal products prepared under hospital exemption with the requirements referred to in paragraph 3.

Or. en

Amendment 34

Proposal for a directive Article 2 – paragraph 5

Text proposed by the Commission

5. If a hospital exemption approval is revoked due to safety or efficacy concerns the competent authority of the Member States that approved the hospital exemption shall inform the Agency and the competent authorities of the other Member States.

Amendment

5. If a hospital exemption approval is revoked due to **quality**, safety or efficacy concerns the competent authority of the Member States that approved the hospital exemption shall inform the Agency and the competent authorities of the other Member States.

Or. en

Amendment 35

Proposal for a directive Article 2 – paragraph 6

Text proposed by the Commission

6. The competent authority of the Member State shall transmit the data related to the use, safety and efficacy of an advanced therapy medicinal product prepared under the hospital exemption approval to the Agency annually. The Agency shall, in collaboration with the competent authorities of Member States and the Commission, set up and maintain a repository of that data.

Amendment

6. The competent authority of the Member State shall transmit the data related to the use, **quality**, safety and efficacy of an advanced therapy medicinal product prepared under the hospital exemption approval to the Agency annually. The Agency shall, in collaboration with the competent authorities of Member States and the Commission, set up and maintain a **publicly accessible** repository of that data,

Amendment 38

Proposal for a directive

Article 4 – paragraph 1 – point 2 – point d

Text proposed by the Commission

(d) chemical, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis;

Amendment

(d) chemical, e.g. elements, ***including radioactive isotopes thereof (radionuclides)***, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis;

Or. en

Amendment 39

Proposal for a directive

Article 4 – paragraph 1 – point 4

Text proposed by the Commission

(4) ‘starting material’ means any material from which an active substance is manufactured or extracted;

Amendment

(4) ‘starting material’ means any material, ***including radioactive materials***, from which an active substance is manufactured or extracted;

Or. en

Amendment 40

Proposal for a directive

Article 4 – paragraph 1 – point 18

Text proposed by the Commission

(18) ‘radiopharmaceutical’ means any medicinal product that, when ready for use, contains ***one or more*** radionuclides ***(radioactive isotopes) included for a medicinal purpose;***

Amendment

(18) ‘radiopharmaceutical’ means any medicinal product that, when ready for use, contains ***a radioactive component and that is intended to treat or diagnose a disease, including radionuclide radiopharmaceuticals and complex radiopharmaceuticals, not including radionuclides used only for radiolabelling***

purposes, medical devices and in-vitro diagnostic devices;

Or. en

Amendment 41

Proposal for a directive

Article 4 – paragraph 1 – point 18 a (new)

Text proposed by the Commission

Amendment

(18a) 'radionuclide radiopharmaceuticals' means a radiopharmaceutical where the radionuclide or its salt is the active substance;

Or. en

Amendment 42

Proposal for a directive

Article 4 – paragraph 1 – point 18 b (new)

Text proposed by the Commission

Amendment

(18b) 'complex radiopharmaceutical' means a radiopharmaceutical where the radionuclide is bound to or within a carrier molecule to achieve the targeted accumulation, including ready-to-use dosage forms and kits for radiopharmaceutical preparation;

Or. en

Amendment 43

Proposal for a directive

Article 4 – paragraph 1 – point 19

Text proposed by the Commission

(19) ‘radionuclide generator’ means any system incorporating a fixed parent radionuclide from which ***is produced*** a daughter radionuclide ***which is to be obtained by elution or by any other method and used in a radiopharmaceutical***;

Amendment

(19) ‘radionuclide generator’ means any system incorporating a fixed parent radionuclide from which a daughter radionuclide ***is produced, where the daughter radionuclide is used either as a medicinal product or as a radionuclide for radiolabelling purposes***;

Or. en

Amendment 44

**Proposal for a directive
Article 4 – paragraph 1 – point 20**

Text proposed by the Commission

(20) ‘kit’ ***means any preparation to be reconstituted or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration***;

Amendment

(20) ‘kit ***for radiopharmaceutical preparation***’ ***means a pre-formulated medicinal product containing all ingredients required to directly prepare a radiopharmaceutical, with the exception of the radionuclide***;

Or. en

Amendment 45

**Proposal for a directive
Article 4 – paragraph 1 – point 21**

Text proposed by the Commission

(21) ‘radionuclide precursor’ ***means any other radionuclide produced for the radio-labelling of another substance prior to administration***;

Amendment

deleted

Or. en

Amendment 46

Proposal for a directive

Article 4 – paragraph 1 – point 26

Text proposed by the Commission

(26) ‘combination of a medicinal product with a product other than a medical device’ means a combination of a medicinal product with a product other than a medical device (as defined by **Regulation** (EU) 2017/745) and where the two are intended for use in the given combination in accordance with the summary of product characteristics;

Amendment

(26) ‘combination of a medicinal product with a product other than a medical device’ means a combination of a medicinal product with a product other than a medical device (as defined by **Regulations** (EU) 2017/745 **and (EU) 2017/746**) and where the two are intended for use in the given combination in accordance with the summary of product characteristics;

Or. en

Amendment 47

Proposal for a directive

Article 4 – paragraph 1 – point 28

Text proposed by the Commission

(28) ‘vaccine’ means any medicinal product that is intended to elicit an immune response for prevention, including post exposure prophylaxis, **and for treatment** of diseases caused by an infectious agent;

Amendment

(28) ‘vaccine’ means any medicinal product that is intended to elicit an immune response for prevention, including post exposure prophylaxis, of diseases caused by an infectious agent;

Or. en

Amendment 48

Proposal for a directive

Article 4 – paragraph 1 – point 30 a (new)

Text proposed by the Commission

Amendment

(30a) ‘platform technology’ means a technology or collection of technologies used in the manufacturing process,

quality control, or testing of medicinal products or their components that rely on prior knowledge and are established under the same underlying scientific principles;

Or. en

Justification

See amendments to new Article 26a.

Amendment 49

Proposal for a directive Article 4 – paragraph 1 – point 30 b (new)

Text proposed by the Commission

Amendment

(30b) ‘platform technology master file’ means a document, prepared by the owner of the platform technology, that contains data of a platform technology for which the underlying scientific principles, under which the platform technology is established, will apply regardless of components added to the platform as part of the manufacturing process for a medicinal product;

Or. en

Justification

See amendments to new Article 26a.

Amendment 50

Proposal for a directive Article 4 – paragraph 1 – point 33

Text proposed by the Commission

Amendment

(33) ‘environmental risk assessment’ means the evaluation of the risks to the environment, *or* risks to public health,

(33) ‘environmental risk assessment’ means the evaluation of the *potential* risks to the environment, *including* risks to

posed by the release of the medicinal product in the environment from the use and disposal of the medicinal product and the identification of risk prevention, limitation and mitigation measures. For medicinal product with an antimicrobial mode of action, the ERA also encompasses an evaluation of the risk for antimicrobial resistance selection in the environment due to the manufacturing, use and disposal of that medicinal product;

public health *arising from risks to the environment*, posed by the release of the medicinal product in the environment from the use and disposal of the medicinal product and the identification of risk prevention, limitation and mitigation measures. For medicinal product with an antimicrobial mode of action, the ERA also encompasses an evaluation of the risk for antimicrobial resistance selection in the environment due to the manufacturing, use and disposal of that medicinal product;

Or. en

Amendment 51

Proposal for a directive Article 4 – paragraph 1 – point 53

Text proposed by the Commission

(53) ‘micro, small and medium-sized enterprises’ means micro, small and medium-sized enterprises as defined in Article 2 of Commission Recommendation 2003/361/EC⁷² ;

⁷² Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

Amendment

(53) ‘micro, small and medium-sized enterprises’ means micro, small and medium-sized enterprises as defined in Article 2 of Commission Recommendation 2003/361/EC⁷² *and, from ... [18 months after the date of entry into force of this Directive], it means micro, small and medium-sized enterprises as defined in the delegated act referred to in Article 58a(1);*

⁷² Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

Or. en

Amendment 52

Proposal for a directive Article 4 – paragraph 1 – point 70

Text proposed by the Commission

(70) ‘public service obligation’ means to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a **very short** time over the whole of the area in question.

Amendment

(70) ‘public service obligation’ means to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a **reasonable** time over the whole of the area in question.

Or. en

Amendment 53

**Proposal for a directive
Article 6 – paragraph 2 a (new)**

Text proposed by the Commission

Amendment

2a. A marketing authorisation may be granted for a medicinal product on the basis of an active substance master file, an additional quality master file or a platform technology master file.

Or. en

Justification

See amendments to new Article 26a.

Amendment 54

**Proposal for a directive
Article 15 – title**

Text proposed by the Commission

Amendment

Fixed dose combination medicinal product, **platform technologies** and multi-medicinal product packages

Fixed dose combination medicinal product and multi-medicinal product packages

Or. en

Justification

See amendments to new Article 26a.

Amendment 55

**Proposal for a directive
Article 15 – paragraph 1**

Text proposed by the Commission

1. Where justified for therapeutic purposes, a marketing authorisation may be granted for a fixed dose combination medicinal product.

Amendment

1. Where justified for ***preventative or*** therapeutic purposes, a marketing authorisation may be granted for a fixed dose combination medicinal product.

Or. en

Amendment 56

**Proposal for a directive
Article 15 – paragraph 2 – subparagraph 1**

Text proposed by the Commission

Where justified for therapeutic purposes, a marketing authorisation may, in exceptional circumstances, be granted for a medicinal product comprised of a fixed component and a variable component that is pre-defined in order to, where appropriate, target different variants of an infectious agent or, where necessary, to tailor the medicinal product to characteristics of an individual patient or a group of patients (***platform technology***).

Amendment

Where justified for ***preventative or*** therapeutic purposes, a marketing authorisation may, in exceptional circumstances, be granted for a medicinal product comprised of a fixed component and a variable component that is pre-defined in order to, where appropriate, target different variants of an infectious agent or, where necessary, to tailor the medicinal product to characteristics of an individual patient or a group of patients.

Or. en

Justification

See amendment to Article 4 – paragraph 1 – point 30 a (new).

Amendment 57

Proposal for a directive Article 16 – paragraph 1

Text proposed by the Commission

1. A marketing authorisation shall be required for ***radionuclide generators, kits, and radionuclide precursors, unless they are used as starting material, active substance or intermediate of radiopharmaceuticals covered by a marketing authorisation under Article 5(1).***

Amendment

1. A marketing authorisation shall be required for radiopharmaceuticals.

Or. en

Amendment 58

Proposal for a directive Article 16 – paragraph 2

Text proposed by the Commission

2. A marketing authorisation shall not be required for a radiopharmaceutical prepared at the time of use by ***a person or by an establishment authorised, according to national legislation, to use such radiopharmaceutical in an approved healthcare establishment exclusively from authorised radionuclide generators, kits or radionuclide precursors in accordance with the manufacturer's instructions.***

Amendment

2. A marketing authorisation shall not be required ***for radionuclides or radionuclide generators solely used for radiolabelling purposes, or*** for a radiopharmaceutical prepared at the time of use by ***an authorised person or establishment using an authorised kit for radiopharmaceutical preparation in combination with a radionuclide or radionuclide generator in accordance with the summary of product characteristics of the kit ('kit-radiolabelling').***

Or. en

Amendment 59

Proposal for a directive Article 22 – paragraph 1

Text proposed by the Commission

1. When preparing the environmental risk assessment ('ERA') to be submitted pursuant to Article 6(2), the applicant shall take into account the scientific guidelines on the environmental risk assessment of medicinal products for human use as referred to in paragraph 6, or provide the reasons for any divergence from the scientific guidelines to the Agency or, as appropriate to the competent authority of the Member State concerned, in a timely manner. Where available, the applicant shall take into account existing ERAs performed under other Union legislation.

Amendment

1. When preparing the environmental risk assessment ('ERA') to be submitted pursuant to Article 6(2), the applicant shall take into account the scientific guidelines on the environmental risk assessment of medicinal products for human use as referred to in paragraph 5, or provide the reasons for any divergence from the scientific guidelines to the Agency or, as appropriate to the competent authority of the Member State concerned, in a timely manner. Where available, the applicant shall take into account existing ERAs performed under other Union legislation.

Or. en

Justification

Incorrect paragraph referenced.

Amendment 60

Proposal for a directive

Article 22 – paragraph 2 – introductory part

Text proposed by the Commission

2. The ERA shall indicate whether the medicinal product or any of its ingredients or other constituents is one of the following substances according to the criteria of Annex I to the Regulation (EC) No 1272/2008:

Amendment

2. The ERA shall indicate whether the medicinal product or any of its ingredients or other constituents is **classified according to** one of the following substances according to the criteria of Annex I to the Regulation (EC) No 1272/2008:

Or. en

Amendment 61

Proposal for a directive

Article 22 – paragraph 2 – subparagraph 1

Text proposed by the Commission

Amendment

or are endocrine *active agents*.

(d) endocrine *disruptors*.

Or. en

Justification

Alignment with the language of Regulation (EC) No 1272/2008.

Amendment 62

Proposal for a directive Article 22 – paragraph 3

Text proposed by the Commission

Amendment

3. The applicant shall also include in the ERA risk mitigation measures to avoid or where it is not possible, limit emissions to air, water and soil of pollutants listed in Directive 2000/60/EC, Directive 2006/118/EC, Directive 2008/105/EC and Directive 2010/75/EU. The applicant shall provide detailed explanation that the proposed mitigation measures are appropriate and sufficient to address the identified risks to the environment.

3. ***Where the ERA identifies a risk to the environment***, the applicant shall also include in the ERA risk mitigation measures to avoid or where it is not possible, limit emissions to air, water and soil of pollutants listed in Directive 2000/60/EC, Directive 2006/118/EC, Directive 2008/105/EC and Directive 2010/75/EU. The applicant shall provide detailed explanation that the proposed mitigation measures are appropriate and sufficient to address the identified risks to the environment.

Or. en

Amendment 63

Proposal for a directive Article 22 – paragraph 4 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

By way of derogation from the first subparagraph, the obligation to conduct a risk assessment for antimicrobial resistance shall only cover the risk for antibiotic resistance. That derogation

shall cease to apply by ... [3 years after the date of entry into force of this Directive].

Or. en

Amendment 64

Proposal for a directive Article 22 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. By ... [18 months after the date of entry into force of this Directive], the Commission shall, after having consulted the Agency, the European Environmental Agency (EEA), and the ECDC, issue guidelines on how to conduct the ERA for antimicrobials other than antibiotics.

Or. en

Amendment 65

Proposal for a directive Article 22 – paragraph 5

Text proposed by the Commission

Amendment

5. The Agency shall draw up scientific guidelines in accordance with Article 138 of [revised Regulation No (EC) 726/2004], to specify technical details regarding the ERA requirements for medicinal products for human use. Where appropriate, the Agency shall consult the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) **and the European Environmental Agency (EEA)** on the drafting of these scientific guidelines.

5. The Agency shall draw up scientific guidelines in accordance with Article 138 of [revised Regulation No (EC) 726/2004], to specify technical details regarding the ERA requirements for medicinal products for human use. Where appropriate, the Agency shall consult the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA), the EEA, **the ECDC and other relevant stakeholders, including those managing residues from medicinal products and their production in the environment,** on the drafting of these scientific guidelines.

Or. en

Amendment 66

Proposal for a directive Article 22 – paragraph 6 – subparagraph 1

Text proposed by the Commission

The marketing authorisation holder shall update the ERA with new information without undue delay to the relevant competent authorities, in accordance with Article 90(2), if new information pertaining to the assessment criteria referred to in Article 29 becomes available and **could lead** to a change of the conclusions of the ERA. The update shall include any relevant information from environmental monitoring, including monitoring under Directive 2000/60/EC, from eco-toxicity studies, from new or updated risk assessments under other Union legislation, as referred to in paragraph 1, and environmental exposure data.

Amendment

The marketing authorisation holder shall update the ERA with new information without undue delay to the relevant competent authorities, in accordance with Article 90(2), if new information pertaining to the assessment criteria referred to in Article 29 becomes available and **leads** to a change of the conclusions of the ERA. The update shall include any relevant information from environmental monitoring, including monitoring under Directive 2000/60/EC, from eco-toxicity studies, from new or updated risk assessments under other Union legislation, as referred to in paragraph 1, and environmental exposure data.

Or. en

Amendment 67

Proposal for a directive Article 22 – paragraph 6 – subparagraph 2

Text proposed by the Commission

For an ERA conducted prior to [OP please insert the date = 18 months after the date of entering into force of this Directive], the competent authority shall request the marketing authorisation holder to update the ERA if missing information has been identified for medicinal products potentially harmful to the environment.

Amendment

For an ERA conducted prior to [OP please insert the date = 18 months after the date of entering into force of this Directive], the competent authority shall request the marketing authorisation holder to update the ERA if missing information has been identified for medicinal products potentially harmful to the environment.
The competent authority may also request the marketing authorisation holder to include in the ERA risk mitigation

measures provided for in paragraph 3.

Or. en

Amendment 68

Proposal for a directive

Article 22 – paragraph 7 a (new)

Text proposed by the Commission

Amendment

7a. The outcome of the assessment of the ERA, including the data submitted by the marketing authorisation holder, shall be made publicly available by the Agency or, as appropriate, by the competent authority of the Member State after deletion of any information of a commercially confidential nature.

Or. en

Amendment 69

Proposal for a directive

Article 23 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Amendment

By [OP please insert the date = 30 months after the date of the entry into force of this Directive] the Agency shall, after consultation with the competent authorities of the Member States, the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environmental Agency (EEA), establish a programme for the ERA to be submitted in accordance with Article 22 of the medicinal products authorised before 30 October 2005 that have not been subject to any ERA and that the Agency has identified as potentially **harmful** to the environment in accordance with paragraph 2.

By [OP please insert the date = 30 months after the date of the entry into force of this Directive] the Agency shall, after consultation with the competent authorities of the Member States, the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environmental Agency (EEA), establish a programme for the ERA to be submitted in accordance with Article 22 of the medicinal products authorised before 30 October 2005 that have not been subject to any ERA and that the Agency has identified as potentially **posing an unacceptable risk** to the environment in accordance with paragraph 2.

Amendment 70

Proposal for a directive

Article 23 – paragraph 1 – subparagraph 2

Text proposed by the Commission

This programme shall be made publicly available by the Agency.

Amendment

This programme ***shall not exceed 10 years and*** shall be made publicly available by the Agency.

Amendment 71

Proposal for a directive

Article 23 – paragraph 2

Text proposed by the Commission

2. The Agency shall set the scientific criteria for the identification of the medicinal products as potentially ***harmful*** to the environment and for the prioritisation of their ERA, using a risk based approach. For this task, the Agency may request from marketing authorisation holders the submission of relevant data or information.

Amendment

2. The Agency shall set the scientific criteria for the identification of the medicinal products as potentially ***posing an unacceptable risk*** to the environment and for the prioritisation of their ERA, using a risk based approach. For this task, the Agency may request from marketing authorisation holders the submission of relevant data or information, ***and may consult with relevant stakeholders including actors managing residues from medicinal products and their production in the environment, in particular water.***

Amendment 72

Proposal for a directive

Article 24 – paragraph 2

Text proposed by the Commission

2. The setting-up of the system of ERA monographs shall be based on a risk-based prioritisation of active substances.

Amendment

2. The setting-up of the system of ERA monographs shall be based on a risk-based prioritisation of active substances **and data requested.**

Or. en

Amendment 73

Proposal for a directive Article 24 – paragraph 4

Text proposed by the Commission

4. The Agency in cooperation with the competent authorities of the Member States shall conduct a proof-of-concept pilot of ERA monographs to be completed within three years after entering into force of this Directive.

Amendment

4. The Agency in cooperation with the competent authorities of the Member States shall conduct a proof-of-concept pilot of ERA monographs to be completed within three years after entering into force of this Directive, **while taking into account outcomes from relevant Union initiatives, such as with regard to animal testing.**

Or. en

Amendment 74

Proposal for a directive Article 24 – paragraph 5 – point e a (new)

Text proposed by the Commission

Amendment

(ea) the risk-based prioritisation of data requirements for active substances, including to avoid unnecessary animal testing.

Or. en

Amendment 75

Proposal for a directive

Article 25 – paragraph 2 – subparagraph 3

Text proposed by the Commission

The Agency shall establish a repository of active substance master files, their assessments reports and their certificates and ensure that personal data is protected. The Agency shall ensure that the competent authorities of the Member State have access to this repository.

Amendment

The Agency shall establish a repository of active substance master files, their assessments reports and their certificates and ensure that personal data **and commercially sensitive information** is protected. The Agency shall ensure that the competent authorities of the Member State have access to this repository.

Or. en

Amendment 76

Proposal for a directive

Article 26 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Marketing authorisation applicants may, instead of submitting the relevant data on an active substance other than a chemical active substance, or on other substances present or used in the manufacture of a medicinal product, required in accordance with Annex II, rely on an additional quality master file, an additional quality master file certificate granted by the Agency in accordance with this Article (‘additional quality master file certificate’), or a certificate confirming that the quality of that substance is suitably controlled by the relevant monograph of the European Pharmacopoeia.

Amendment

Marketing authorisation applicants may, instead of submitting the relevant data on an active substance other than a chemical active substance, or on other substances present or used in the manufacture of a medicinal product, **including raw materials and starting materials used for the manufacturing of cell therapies and gene therapies**, required in accordance with Annex II, rely on an additional quality master file, an additional quality master file certificate granted by the Agency in accordance with this Article (‘additional quality master file certificate’), or a certificate confirming that the quality of that substance is suitably controlled by the relevant monograph of the European Pharmacopoeia.

Or. en

Amendment 77

Proposal for a directive Article 26 – paragraph 3 – point b

Text proposed by the Commission

(b) additional quality master files for which a certificate may be used in order to provide specific information on the quality of a substance present or used in the manufacture of a medicinal product;

Amendment

(b) additional quality master files for which a certificate may be used in order to provide specific information on the quality of a substance present or used in the manufacture of a medicinal product, ***including cell therapies and gene therapies***;

Or. en

Amendment 78

Proposal for a directive Article 26 a (new)

Text proposed by the Commission

Amendment

Article 26a

Additional platform technology master files

- 1. Marketing authorisation applicants may, instead of submitting the relevant data on the quality, safety and efficacy of a medicinal product, required in accordance with Annex II, rely on an additional platform technology master file or an additional platform technology master file certificate granted by the Agency in accordance with this Article ('additional platform technology master file certificate').***
- 2. Article 25(1) to (5), (7) and (8) shall also apply mutatis mutandis to additional platform technology master file certification.***
- 3. The description of the platform technology master file shall represent the applicant's basis for relevant data on***

quality, safety and efficacy of the medicinal product as required in Annex II. To adequately describe the platform technology master file, appropriate information as laid down in scientific guidelines published by the Agency shall be provided.

4. The Commission is empowered to adopt delegated acts in accordance with Article 215 to supplement this Directive by specifying:

(a) the rules governing the content and format of the application for an additional platform technology master file certificate;

(b) additional platform technology master files for which a certificate may be used in order to provide specific information on the platform technology on the basis of which a substance present or used in the manufacture of a medicinal product is manufactured;

(c) the rules for the examination of applications for making publicly available of additional platform technology master file certificates;

(d) the rules for introducing changes to the additional platform technology master file and the certificate;

(e) the rules on access for competent authorities of the Member State to the additional platform technology master file and its assessment report;

(f) the rules on access for marketing authorisation applicants and marketing authorisation holders relying on a additional platform technology master file certificate to the additional platform technology master file and to the assessment report.

5. The Agency shall develop and publish scientific guidelines on the requirements for an additional platform technology master file.

6. *If requested by the Agency, the manufacturer of a substance present or used in the manufacturing of a medicinal product for which an application for an additional platform technology master file certificate has been submitted or the additional platform technology master file certificate holder shall undergo an inspection to verify the information contained in the application or the master file.*

If the holder of the additional platform technology master file refuses to undergo such an inspection, the Agency may suspend or terminate the application for the additional platform technology master file certificate.

Or. en

Amendment 79

Proposal for a directive

Article 44 – paragraph 1 – subparagraph 1 – point h

Text proposed by the Commission

(h) to conduct post-authorisation environmental risk assessment studies, collection of monitoring data or information on use, where identified or potential concerns about risks to the environment *or* public health, **including** antimicrobial resistance need to be further investigated after the medicinal product has been marketed;

Amendment

(h) to conduct post-authorisation environmental risk assessment studies, collection of monitoring data or information on use, where identified or potential concerns about risks to the environment, **including** public health, **and in particular** antimicrobial resistance need to be further investigated after the medicinal product has been marketed;

Or. en

Amendment 80

Proposal for a directive

Article 47 – paragraph 1 – point d

Text proposed by the Commission

Amendment

(d) the environmental risk assessment is incomplete or insufficiently substantiated by the applicant or if the risks identified in the environmental risk assessment have not been sufficiently addressed by the applicant;

deleted

Or. en

Amendment 81

**Proposal for a directive
Article 47 – paragraph 1 a (new)**

Text proposed by the Commission

Amendment

1a. The national marketing authorisation may furthermore be refused if, after verification of the particulars and documentations referred to in Article 6 and subject to the specific requirements laid down in Articles 9 to 14, the view is taken that the environmental risk assessment is incomplete or insufficiently substantiated by the applicant or if the risks identified in the environmental risk assessment have not been sufficiently addressed by the applicant and the competent authority deems that post-authorisation environmental risk assessment studies in accordance with Article 44(1), point (h), would be an insufficient measure to ensure environmental protection.

Or. en

Amendment 82

**Proposal for a directive
Article 51 – paragraph 1 – point e**

Text proposed by the Commission

(e) is an antimicrobial; *or*

Amendment

(e) is an antimicrobial *of systemic administration*;

Or. en

Amendment 83

Proposal for a directive

Article 51 – paragraph 1 – point e a (new)

Text proposed by the Commission

Amendment

(ea) is an antibiotic; or

Or. en

Amendment 84

Proposal for a directive

Article 56 – paragraph 3 – subparagraph 1

Text proposed by the Commission

Amendment

The marketing authorisation holder of a medicinal product placed on the market in a Member State shall, within the limits of its responsibility, ensure appropriate and continued supplies of that medicinal product to wholesale distributors, pharmacies or persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.

The marketing authorisation holder of a medicinal product placed on the market in a Member State shall, within the limits of its responsibility, ensure appropriate and continued supplies of that medicinal product to wholesale distributors *in accordance with Articles 166 and 167*, pharmacies or persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.

Or. en

Amendment 85

Proposal for a directive Article 57 – paragraph 1

Text proposed by the Commission

1. The marketing authorisation holder shall declare to the public any direct financial support received from any public authority or publicly funded body, in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support.

Amendment

1. The marketing authorisation holder shall declare to the public any direct financial support received from any public authority or publicly funded body ***of the Union***, in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support.

Or. en

Amendment 86

Proposal for a directive Article 57 – paragraph 2 – point a – point ii

Text proposed by the Commission

(ii) the public authority or publicly funded body that provided the financial support referred to in point (i);

Amendment

(ii) the public authority or publicly funded body ***of the Union*** that provided the financial support referred to in point (i);

Or. en

Amendment 87

Proposal for a directive Article 57 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6a. The Agency shall provide a publicly accessible website to facilitate access to the electronic links communicated to the Agency in accordance with paragraphs 2 and 3,

sorted, where relevant, by medicine and by Member State.

Or. en

Amendment 88

Proposal for a directive Article 58 a (new)

Text proposed by the Commission

Amendment

Article 58a

Obligation to submit an application for pricing and reimbursement in all Member States

1. The marketing authorisation holder shall, upon request by a Member State in which the marketing authorisation is valid, submit in good faith an application for pricing and reimbursement no later than two years from the date when the Member State made its request, or within four years from that date for any of the following entities:

- (i) SMEs;***
- (ii) entities not engaged in an economic activity ('not-for-profit entity');***
and
- (iii) undertakings that, by the time of granting the marketing authorisation, have received not more than seven centralised marketing authorisations for the undertaking concerned or, in the case of an undertaking belonging to a group, for the group of which it is part, since the establishment of the undertaking or the group, whichever is earliest.***

For the purposes of this Directive and [revised Regulation (EC) No 726/2004], the Commission shall by ... [18 months after the date of entry into force of this Directive] adopt delegated acts in

accordance with Article 215 to supplement this Directive by laying down the criteria to qualify as a micro, small and medium-sized enterprise, taking into account the specificities of enterprises of this sector within the Union.

The marketing authorisation holder shall notify that it fulfilled the obligations set out in the first subparagraph through the EU Access to Medicines Notification System provided for in Article 58b.

2. For the purposes of paragraph 1 of this Article, Member States shall make their request within two years of the granting of a marketing authorisation. Following the filing for pricing and reimbursement by the marketing authorisation holder, Directive 89/105/EEC shall apply. Where a Member State has not complied with the timelines laid down in Directive 89/105/EEC, the obligation on the marketing authorisation holder set out in this Article shall be considered to be fulfilled in that Member State.

3. By way of derogation from paragraph 1, the marketing authorisation holder for a designated orphan medicinal product or for an advanced therapy medicinal product may choose instead:

(a) to make a medicinal product directly available to patients and the prescribing doctors who requested it; or

(b) to submit an application for pricing and reimbursement only in the Member States where the relevant patient population has been identified.

4. Following agreement between a Member State and a marketing authorisation holder, timelines that are different from those set out in paragraphs 1 and 2 may apply. A Member State may choose, after making a request in accordance with paragraph 1, to issue a product-specific waiver after which the obligation to submit an application shall

cease.

5. The Commission shall, after consultation of the Agency, adopt by means of implementing acts a list of products to be exempted from the obligations set out in this Article. Inclusion of a medicinal product in that list may be based on criteria such as the administration of a medicinal product in most Member States being impracticable. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).

6. Where a marketing authorisation is transferred to a different legal entity before the end of the period referred to in paragraph 1, the obligations shall be transferred to the new marketing authorisation holder.

7. The Commission shall by means of implementing acts establish a conciliation mechanism to facilitate discussions between applicants and Member States to resolve potential disputes related to the submission of applications for pricing and reimbursement and Directive 89/105/EEC. In the event of continued disagreement between an applicant and a Member State regarding the fulfilment of the obligations set out in this Article, the Commission shall be empowered to issue a legally binding Commission decision following an opinion of the Agency.

Or. en

Amendment 89

Proposal for a directive Article 58 b (new)

Text proposed by the Commission

Amendment

Article 58b

EU Access to Medicines Notification

System

- 1. The Commission shall, in collaboration with the Member States, set up and maintain an electronic notification system (the “EU Access to Medicines Notification System”) as a single-entry point for the notification of compliance with the obligations set out in Article 58a. The EU Access to Medicines Notification System shall be interoperable with the other Union-wide data repositories for medicinal products.**
- 2. The marketing authorisation holder shall use the EU Access to Medicines Notification System to notify their compliance with the obligations set out in Article 58a. In the Member States where the marketing authorisation is valid, the national competent authority shall use the EU Access to Medicines Notification System to indicate that the marketing authorisation holder has fulfilled its obligations set out in Article 58a.**
- 3. By ... [3 years following the date of entry into force of this Directive], the Commission shall adopt implementing acts to establish technical and organisational requirements, including on security aspects and data governance, which are necessary for the practical implementation of the EU Access to Medicines Notification System. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).**
- 4. By ... [5 years after the date of entry into force of this Directive] and every 3 years thereafter, the Commission shall present a report to the European Parliament and the Council on the use and functioning of the EU Access to Medicines Notification System.**
- 5. By ... [5 years after the date of entry into force of this Directive], the Commission shall assess the feasibility of extending the EU Access to Medicines**

Notification System to other areas of the process for pricing of medicinal products as set out in Directive 89/105/EEC and, if appropriate, adopt implementing acts to establish this extended system. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).

Or. en

Amendment 90

Proposal for a directive Article 63 – paragraph 3

Text proposed by the Commission

3. Member States may decide that the package leaflet shall be made available ***in paper format or*** electronically, or both. In the absence of such specific rules in a Member State, a package leaflet in paper format ***shall be included*** in the packaging of a medicinal product. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients.

Amendment

3. Member States may decide that the package leaflet shall be made available electronically, or both ***in paper format and electronically***. In the absence of such specific rules in a Member State, a package leaflet ***shall be made available electronically and be included*** in paper format in the packaging of a medicinal product. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients ***as well as written and designed in a clear and understandable way***.

Or. en

Amendment 91

Proposal for a directive Article 63 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. If a Member State has decided that the package leaflet is only to be made available electronically, patients shall be made aware of their right to a printed copy of the package leaflet. If the package leaflet is only to be made available electronically, a package leaflet in paper format may still be provided on a voluntary basis by the marketing authorisation holder in addition to the electronic package leaflet.

Or. en

Amendment 92

Proposal for a directive Article 63 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. Where the medicinal product is not intended to be delivered directly to and administered by the patient, the Commission is empowered to adopt delegated acts in accordance with Article 215 to amend paragraph 3 of this Article by making only the electronic version of the package leaflet mandatory in this specific context. In such a case, a package leaflet in paper format may still be provided on a voluntary basis by the marketing authorisation holder in addition to the electronic package leaflet.

Or. en

Amendment 93

Proposal for a directive Article 63 – paragraph 5

Text proposed by the Commission

Amendment

5. The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend paragraph 3 by making mandatory the electronic version of the package leaflet. That delegated act shall also establish the patient's right to a printed copy of the package leaflet upon request and free of charge. The delegation of powers shall apply as of [OP please insert the date = five years following 18 months after the date of entering into force of this Directive].

deleted

Or. en

Amendment 94

Proposal for a directive Article 63 – paragraph 6

Text proposed by the Commission

Amendment

6. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies.

6. By ... [12 months after the date of entry into force of this Directive], the Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies.

Or. en

Amendment 95

Proposal for a directive Article 63 – paragraph 7

Text proposed by the Commission

7. **Where** the package leaflet **is made available** electronically, the individual right to privacy shall be ensured. Any technology giving access to the information shall not allow the identification or tracking of individuals, nor shall it be used for commercial purposes.

Amendment

7. **When accessing** the package leaflet electronically, the individual right to privacy shall be ensured. Any technology giving access to the information shall **ensure the protection of personal data according to relevant Union legislation, and shall** not allow the identification, **profiling** or tracking of individuals, nor shall it be used for commercial purposes **including advertising and marketing activities**.

Or. en

Amendment 96

Proposal for a directive Article 63 – paragraph 7 a (new)

Text proposed by the Commission

7a. **The Agency shall develop a system providing public access to the electronic version of package leaflets. By ... [12 months after the date of entry into force of this Directive], the system shall be accessible in all Member States.**

Amendment

7a. **The Agency shall develop a system providing public access to the electronic version of package leaflets. By ... [12 months after the date of entry into force of this Directive], the system shall be accessible in all Member States.**

Or. en

Amendment 97

Proposal for a directive Article 64 – paragraph 3

Text proposed by the Commission

3. **The package leaflet shall reflect the results of consultations** with target patient groups to ensure that **it** is legible, clear and easy to use.

Amendment

3. **Following a consultation** with target patient groups **and other relevant stakeholders, the Commission shall adopt guidelines** to ensure that **the package leaflet** is legible, clear and easy to use **as**

well as on the need for and modalities of further user testing.

Or. en

Amendment 98

Proposal for a directive

Article 67 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Medicinal products not subject to prescription shall not bear the safety features referred to in Annex IV, unless, by way of exception, they have been listed in accordance with the procedure referred to in paragraph 2, second subparagraph, point (b).

Amendment

Medicinal products not subject to prescription shall not bear the safety features referred to in Annex IV, unless, by way of exception, they have been listed in accordance with the procedure referred to in paragraph 2, second subparagraph, point (b), *or where the marketing authorisation holder chooses to do so voluntarily.*

Or. en

Amendment 99

Proposal for a directive

Article 67 – paragraph 7 a (new)

Text proposed by the Commission

Amendment

7a. *For the purpose of patient safety, Member States may decide that medicinal products imported or distributed in parallel shall be repackaged in new outer packaging.*

Or. en

Amendment 100

Proposal for a directive

Article 69 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Member States *may decide* that the awareness card *shall be* made available in paper format or electronically, *or both*. In the absence of such specific rules in a Member State, an awareness card in paper format shall be included in the packaging of an antimicrobial.

Amendment

Member States *shall ensure* that the awareness card *is* made available in paper format or *both in paper format and* electronically. In the absence of such specific rules in a Member State, an awareness card in paper format shall be included in the packaging of an antimicrobial.

Or. en

Amendment 101

**Proposal for a directive
Article 74 – paragraph 4 a (new)**

Text proposed by the Commission

Amendment

4a. *Where a competent authority grants a full or partial exemption to the language requirements in accordance with paragraph 4, patients' right to a copy of the document in the official language of the Member State shall be guaranteed upon request and free of charge.*

Or. en

Amendment 102

**Proposal for a directive
Article 80 – paragraph 4**

Text proposed by the Commission

Amendment

4. By way of derogation from the paragraphs 1 and 2, when a compulsory licence has been granted by a relevant authority in the Union to a party to address a public health emergency, the data and market protection shall be suspended with regard to that party insofar as the

4. By way of derogation from the paragraphs 1 and 2, when a compulsory licence has been granted by a relevant authority in the Union to a party to address a public health emergency, the data and market protection shall be suspended *for the indication that is relevant to the public*

compulsory licence requires, and during the duration period of the compulsory licence.

health emergency with regard to that party insofar as the compulsory licence requires, **in the relevant Member States** and during the duration period of the compulsory licence.

Or. en

Amendment 103

Proposal for a directive Article 80 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. The marketing authorisation holder for the medicinal product for which a compulsory licence has been granted shall be informed of the decision without delay.

Or. en

Amendment 104

Proposal for a directive Article 81 – paragraph 1

Text proposed by the Commission

Amendment

1. The regulatory data protection period shall be **six** years from the date when the marketing authorisation for that medicinal product was granted in accordance with Article 6(2). For marketing authorisations that belong to the same global marketing authorisation the period of data protection shall start from the date when the initial marketing authorisation was granted in the Union.

1. The regulatory data protection period shall be **nine** years from the date when the marketing authorisation for that medicinal product was granted in accordance with Article 6(2). For marketing authorisations that belong to the same global marketing authorisation the period of data protection shall start from the date when the initial marketing authorisation was granted in the Union.

Or. en

Amendment 105

Proposal for a directive

Article 81 – paragraph 2 – subparagraph 1 – point a

Text proposed by the Commission

Amendment

(a) **24 months, where the marketing authorisation holder demonstrates that the conditions referred to in Article 82(1) are fulfilled within two years, from the date when the marketing authorisation was granted or, within three years from that date for any of the following entities:** **deleted**

(i) **SMEs within the meaning of Commission Recommendation 2003/361/EC;**

(ii) **entities not engaged in an economic activity ('not-for-profit entity');**
and

(iii) **undertakings that, by the time of granting of a marketing authorisation, have received not more than five centralised marketing authorisations for the undertaking concerned or, in the case of an undertaking belonging to a group, for the group of which it is part, since the establishment of the undertaking or the group, whichever is earliest.**

Or. en

Justification

See amendments to new Article 58a.

Amendment 106

Proposal for a directive

Article 81 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission

Amendment

(b) **six months, where the marketing authorisation applicant demonstrates at the time of the initial marketing authorisation**

(b) **12 months, where the marketing authorisation applicant demonstrates at the time of the initial marketing authorisation**

application that the medicinal product addresses an unmet medical need as referred to in Article 83;

application that the medicinal product addresses an unmet medical need as referred to in Article 83;

Or. en

Amendment 107

Proposal for a directive

Article 81 – paragraph 2 – subparagraph 1 – point c

Text proposed by the Commission

(c) six months, for medicinal products ***containing a new active substance***, where the clinical trials supporting the ***initial*** marketing authorisation application use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency;

Amendment

(c) six months, for medicinal products where the clinical trials supporting the marketing authorisation application use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency;

Or. en

Amendment 108

Proposal for a directive

Article 82

Text proposed by the Commission

[...]

Amendment

deleted

Or. en

Justification

See amendments to new Article 58a.

Amendment 109

Proposal for a directive

Article 83 – paragraph 1 – introductory part

Text proposed by the Commission

1. A medicinal product shall be considered as addressing an unmet medical need if at least one of its therapeutic indications relates to a life threatening or severely debilitating disease and the following conditions are met:

Amendment

1. A medicinal product shall be considered as addressing an unmet medical need if at least one of its therapeutic indications relates to a ***progressive***, life threatening or severely debilitating disease and the following conditions are met:

Or. en

Amendment 110

**Proposal for a directive
Article 83 – paragraph 1 – point a**

Text proposed by the Commission

(a) there is no medicinal product authorised in the Union for such disease, or, where despite medicinal products being authorised for such disease in the Union, the disease is associated with a remaining high morbidity ***or*** mortality;

Amendment

(a) there is no medicinal product authorised in the Union for such disease, or, where despite medicinal products being authorised for such disease in the Union, the disease is associated with a remaining high morbidity, ***high*** mortality ***or significant negative impact on quality of life***;

Or. en

Amendment 111

**Proposal for a directive
Article 83 – paragraph 1 – point b**

Text proposed by the Commission

(b) the use of the medicinal product results in ***a meaningful reduction in disease morbidity or mortality for the relevant patient population.***

Amendment

(b) the use of the medicinal product results in:

Or. en

Amendment 112

Proposal for a directive

Article 83 – paragraph 1 – point b – point i (new)

Text proposed by the Commission

Amendment

(i) a meaningful reduction in disease morbidity, mortality, severity or long term side effects for the relevant patient population; or

Or. en

Amendment 113

Proposal for a directive

Article 83 – paragraph 1 – point b – point ii (new)

Text proposed by the Commission

Amendment

(ii) a meaningful positive impact on quality of life; or

Or. en

Amendment 114

Proposal for a directive

Article 83 – paragraph 1 – point b – point iii (new)

Text proposed by the Commission

Amendment

(iii) a meaningful delay of the onset of the disease or its complications.

Or. en

Amendment 115

Proposal for a directive

Article 83 – paragraph 3

Text proposed by the Commission

3. Where the Agency adopts scientific guidelines for the application of this Article it shall consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004].

Amendment

3. Where the Agency adopts scientific guidelines for the application of this Article it shall consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004], ***representatives of patients' organisations in the relevant disease areas, healthcare professionals, representatives of pharmaceutical industry and other relevant stakeholders.***

Or. en

Amendment 116

Proposal for a directive

Article 85 – paragraph 1 – point a – introductory part

Text proposed by the Commission

(a) studies, trials and other activities conducted to generate data for an application, for:

Amendment

(a) studies, trials and other ***necessary*** activities conducted to generate data for an application, for:

Or. en

Amendment 117

Proposal for a directive

Article 85 – paragraph 1 – point a – point i

Text proposed by the Commission

(i) a marketing authorisation ***of generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent variations;***

Amendment

(i) a marketing authorisation;

Or. en

Amendment 118

Proposal for a directive

Article 85 – paragraph 1 – point a – point iii

Text proposed by the Commission

(iii) pricing and reimbursement.

Amendment

deleted

Or. en

Amendment 119

Proposal for a directive

Article 85 – paragraph 1 – point b

Text proposed by the Commission

(b) the activities conducted exclusively for the purposes set out in point (a), may cover the ***submission of the application for a marketing authorisation and the offer***, manufacture, sale, supply, storage, import, use and purchase of patented medicinal products or processes, including by third party suppliers and service providers.

Amendment

(b) the activities conducted exclusively for the purposes set out in point (a), may cover the manufacture, sale, supply, storage, import, use and purchase of patented medicinal products or processes, including by third party suppliers and service providers.

Or. en

Amendment 120

Proposal for a directive

Article 86 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Where an application for marketing authorisation, includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a six-month extension of the period referred to in Article 13, paragraphs 1 and 2 of

Amendment

Where an application for marketing authorisation, includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a six-month extension of the period referred to in Article 13, paragraphs 1 and 2 of

[Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted].

[Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted]. ***Where the agreed paediatric investigation plan is conducted in relation to a disease that is different from the one for which the medicinal product is intended in the adult population, the holder of the patent or supplementary protection certificate shall be entitled to a 12-month extension of the period.***

Or. en

Amendment 121

Proposal for a directive Article 94 – paragraph 1

Text proposed by the Commission

1. On the basis of relevant paediatric clinical studies received in accordance with Article 45(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council⁷⁶, the competent authorities of the Member States may vary the marketing authorisation of the medicinal product concerned accordingly and update the summary of product characteristics and package leaflet of the medicinal product concerned. The competent authorities shall exchange information regarding the studies submitted and, as appropriate, their implications for any marketing authorisations concerned.

⁷⁶ Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).

Amendment

1. On the basis of relevant paediatric clinical studies received in accordance with Article 45(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council⁷⁶, the competent authorities of the Member States may, ***following a consultation of the marketing authorisation holder***, vary the marketing authorisation of the medicinal product concerned accordingly and update the summary of product characteristics and package leaflet of the medicinal product concerned. The competent authorities shall exchange information regarding the studies submitted and, as appropriate, their implications for any marketing authorisations concerned.

⁷⁶ Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).

Amendment 122

Proposal for a directive Article 105 – paragraph 2

Text proposed by the Commission

2. Marketing authorisation holders shall not refuse to consider reports of suspected adverse reactions received electronically or by any other appropriate means from patients or healthcare professionals.

Amendment

2. Marketing authorisation holders shall not refuse to consider reports of suspected adverse reactions received electronically or by any other appropriate means from patients, ***carers or other relevant persons, such as family members,*** or healthcare professionals.

Or. en

Amendment 123

Proposal for a directive Article 147 – paragraph 1 – subparagraph 1 – point j a (new)

Text proposed by the Commission

Amendment

(ja) use an appropriate wastewater treatment system.

Or. en

Amendment 124

Proposal for a directive Article 163 – paragraph 1

Text proposed by the Commission

1. The competent authority of the Member State concerned shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to an authorisation to engage in activity as a wholesaler in

Amendment

1. The competent authority of the Member State concerned shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to an authorisation to engage in activity as a wholesaler in

medicinal products (“wholesale distribution authorisation”). The wholesale distribution authorisation shall indicate the premises, the medicinal products and the wholesale distribution operations for which it is valid.

medicinal products (“wholesale distribution authorisation”). The wholesale distribution authorisation shall indicate the premises, the *categories of* medicinal products and the wholesale distribution operations for which it is valid.

Or. en

Amendment 125

Proposal for a directive Article 166 – paragraph 1 – point l

Text proposed by the Commission

Amendment

(l) continuously guarantee the appropriate and continued supply of an adequate range of medicinal products to meet the requirements of a specific geographical area, and deliver the supplies requested over the whole of the area in question, within a reasonable timeframe, which shall be defined in the national legislation;

deleted

Or. en

Justification

See amendment to Article 166 – paragraph 1 a (new).

Amendment 126

Proposal for a directive Article 166 – paragraph 1 – point m

Text proposed by the Commission

Amendment

(m) cooperate with marketing authorisation holders and competent authorities of the Member States on the security of supply.

(m) cooperate with ***all relevant stakeholders, including*** marketing authorisation holders and competent authorities of the Member States on the security of supply.

Amendment 127

Proposal for a directive Article 166 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Member States shall designate wholesale distribution authorisation holders who shall continuously guarantee the appropriate and continued supply of an adequate range of medicinal products to meet the requirements of a specific geographical area, and deliver the supplies requested over the whole of the area in question, within a reasonable timeframe, which shall be defined in national legislation.

Or. en

Amendment 128

Proposal for a directive Article 177 – paragraph 4

Text proposed by the Commission

Amendment

4. The prohibition contained in paragraph 1 shall not apply to vaccination campaigns ***carried out by the industry and*** approved by the competent authorities of the Member States.

4. The prohibition contained in paragraph 1 shall not apply to vaccination campaigns approved by the competent authorities of the Member States.

Or. en

Amendment 129

Proposal for a directive Article 185 – paragraph 1 – point b

Text proposed by the Commission

(b) any supply of samples shall be in response to a written request, signed and dated, from the persons qualified to prescribe or supply medicinal products;

Amendment

(b) any supply of samples shall be in response to a written **or electronic** request, signed and dated, from the persons qualified to prescribe or supply medicinal products;

Or. en

Amendment 130

Proposal for a directive

Article 188 – paragraph 15 a (new)

Text proposed by the Commission

Amendment

15a. The Agency shall draw up guidelines on the use of the Union database.

Or. en

Amendment 131

Proposal for a directive

Article 195 – paragraph 2

Text proposed by the Commission

Amendment

2. The competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission may suspend, **revoke** or vary a marketing authorisation if a serious risk to the environment **or** public health has been identified and not sufficiently addressed by the marketing authorisation holder.

2. The competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission may suspend or vary a marketing authorisation if a serious risk to the environment, **including** public health, has been identified and not sufficiently addressed by the marketing authorisation holder. **The competent authorities of the Member States or, in the case of a centralised marketing authorisation, the Commission may revoke a marketing authorisation in such cases only if it deems that those risks clearly outweigh**

the loss of positive therapeutic effects of the medicinal product for the concerned patient population and the risks cannot be mitigated following a decision of suspension or modification.

Or. en

Amendment 132

Proposal for a directive Article 206 – paragraph 2 – point e a (new)

Text proposed by the Commission

Amendment

(ea) non-compliance with the obligations laid down in Article 58a shall be subject to the imposition of effective, proportionate and dissuasive financial penalties.

Or. en

Amendment 133

Proposal for a directive Article 207 – title

Text proposed by the Commission

Amendment

Collection of unused or expired medicinal products

Collection **and management** of unused or expired medicinal products

Or. en

Amendment 134

Proposal for a directive Article 207 – paragraph 1

Text proposed by the Commission

Amendment

Member States shall ensure that

1. Member States shall ensure that

appropriate collection systems are in place for medicinal products that are unused or have expired.

appropriate collection systems are in place for medicinal products that are unused or have expired ***and that the collected medicinal products are managed properly without any technically avoidable leakage to the environment.***

Or. en

Amendment 135

Proposal for a directive Article 207 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. By ... [18 months after the date of entry into force of this Directive], Member States shall draw up national plans including measures designed to:

(a) monitor the rates of correct and incorrect disposal of unused and expired medicinal products;

(b) inform the general public about the environmental risks associated with incorrect disposal of medicinal products, in particular those that contain substances referred to in Article 22(2);

(c) inform healthcare professionals about the environmental risks associated with incorrect disposal of unused or expired medicinal products, in particular those that contain substances referred to in Article 22(2);

(d) increase the rate of correct disposal of unused or expired medicinal products; and

(e) designate public and private actors responsible for the collection systems referred to in paragraph 1.

Or. en

Amendment 136

Proposal for a directive Article 207 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

1b. The national plans shall be submitted to the Commission.

Or. en

Amendment 137

Proposal for a directive Article 207 – paragraph 1 c (new)

Text proposed by the Commission

Amendment

1c. From ... [five years after the date of entry into force of this Directive], the Commission is empowered to adopt delegated acts in accordance with Article 215 to amend paragraph 1a of this Article by supplementing or modifying the measures provided for in that paragraph if it is necessary to minimise the environmental risks posed by incorrect disposal of unused or expired medicinal products.

Or. en

Amendment 138

Proposal for a directive Article 215 – paragraph 2 – subparagraph 1

Text proposed by the Commission

Amendment

The power to adopt delegated acts referred to in Articles 4(2), 24(5), 25(9), 26(3), **28, paragraphs 2 and 3, 27(3), 63(5), 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161, 210(4) and 213** shall be conferred on

The power to adopt delegated acts referred to in Articles 4(2), 24(5), 25(9), 26(3), **26a(4), 27(3), 28(2) and (3), 58a(1), 63(4a), 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161, 207(1c), 210(4) and**

the Commission for a period of five years from [OP please insert the date of the entry into force of this Directive]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

213 shall be conferred on the Commission for a period of five years from [OP please insert the date of the entry into force of this Directive]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

Or. en

Amendment 139

Proposal for a directive Article 215 – paragraph 3

Text proposed by the Commission

3. The delegation of power referred to in Articles 4(2), 24(5), 25(9), 26(3), 27(3), **28, paragraphs 2 and 3, 63(5)**, 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161, 210(4) and 213 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Amendment

3. The delegation of power referred to in Articles 4(2), 24(5), 25(9), 26(3), **26a(4)**, 27(3), **28(2) and (3), 58a(1), 63(4a)**, 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161, **207(1c)**, 210(4) and 213 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Or. en

Amendment 140

Proposal for a directive Article 215 – paragraph 6

Text proposed by the Commission

6. A delegated act adopted pursuant to Articles 6(2), 26(3), 24(5), **28, paragraphs 2 and 3, 27(3), 63(5)**, 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161, 210(4) and 213 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Amendment

6. A delegated act adopted pursuant to Articles 6(2), 26(3), 24(5), **26a(4), 27(3), 28(2) and (3), 58a(1), 63(4a)**, 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161, **207(1c)**, 210(4) and 213 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Or. en

Amendment 141

**Proposal for a directive
Annex IV – paragraph 1 – point a**

Text proposed by the Commission

(a) the name of the medicinal product, including in Braille, followed by its strength and pharmaceutical form, and, if appropriate, whether it is intended for babies, children or adults; where the medicinal product contains up to three active substances, the international non-proprietary name (INN) shall be included, or, if one does not exist, the common name;

Amendment

(a) the name of the medicinal product, including in Braille, followed by its strength and pharmaceutical form, and, if appropriate, whether it is intended for babies, children or adults; where the medicinal product contains up to three active substances, the international non-proprietary name (INN) shall be included, ***unless it is already part of the name of the medicinal product***, or, if one does not exist, the common name;

Or. en

Amendment 142

**Proposal for a directive
Annex VI – paragraph 1 – point 2 a (new)**

Text proposed by the Commission

Amendment

***(2a) a key information section
reflecting the results of consultations with
patients' organisations to ensure that the
leaflet is legible, clear and easy to use;***

Or. en

EXPLANATORY STATEMENT

The Union general pharmaceutical legislation was established in 1965 with the dual objective of safeguarding public health and harmonising the internal market for medicines. The latest proposal of the European Commission for revision of this legislation includes a new Directive and a new Regulation to replace pharmaceutical legislation currently in force, with the overall objectives of promoting innovation, ensuring access to innovative and established medicines for patients, and creating a balanced and competitive system that keeps medicines affordable for health systems while rewarding innovation. Of the ‘Pharmaceutical Package’, this Directive contains all the requirements for authorisation, monitoring, labelling and regulatory protection, placing on the market and other regulatory procedures for all medicines authorised at EU and national level.

The Rapporteur supports the objectives of the European Commission’s proposal and finds that a revision of current Union general pharmaceutical legislation comes at the right time: Europe is increasingly falling behind other regions in pharmaceutical research and development investments, novel technologies challenge the existing legislative framework, and the COVID-19 pandemic demonstrated the need for timely and equitable access to medicines.

Incentivising Innovation

The Rapporteur believes that increasing the number of innovative medicinal products available to Europeans is of crucial benefit to patients and society. In this regard, the Directive must present a framework for rewarding innovation which is attractive to the global pharmaceutical industry, including the wider research-based life-science environment.

Making Europe competitive is an objective which requires a multifactorial solution. However, among the key factors, which is within the scope of this Directive, is the system of incentives and namely the regulatory data protection. Regulatory data protection affects companies’ decisions to invest in innovation and to bring scientific innovation to launch on the Union market. In this regard, the Rapporteur finds that the level of regulatory data protection offered on the Union market should be competitive with what is being offered in other markets. Furthermore, there should be certainty and long-term predictability regarding the level of regulatory data protection to be expected, which means that a significant amount of the total regulatory data protection should remain within the ‘baseline’.

The Rapporteur agrees with the European Commission’s proposal that further incentives on top of an attractive baseline of regulatory data protection may help steer innovation and finds that a definition of unmet medical need should be considered from both the individual patient and societal perspectives. That is, innovation for unmet medical need should be sufficiently incentivised, while the definitions applied for deciding which medicinal products address an unmet medical need should consider the patient perspective centrally. In this regard, the Rapporteur finds that the concept of ‘quality of life’ of patients should be considered.

Outside of regulatory data protection, the Rapporteur also proposes to increase the reward for completion of a paediatric investigation plan where this is completed for a different disease than the one for which a medicinal product is intended in the adult population.

Access to Medicines

The European Commission has proposed an incentive which will grant a prolongation of data protection if a medicinal product is supplied in accordance with the needs of the Member States concerned within two years from the marketing authorisation (or within three years in the case of SMEs, not-for-profit entities or companies with limited experience in the EU system). The Rapporteur opposes this measure, by which the European Commission intends to promote access to medicinal products. Firstly, because the release and continuous supply of medicinal products is not only within the control of the marketing authorisation holder but also relies on the Member State competent authorities. Thus, it would be disproportionate to place all responsibility, and direct consequences, for a failure to launch only on the marketing authorisation holder. Secondly, linking the failure to comply with the conditionality of supply in every Member State to losing out on regulatory data protection will be to the detriment of innovation, as described above. Finally, the Rapporteur is concerned about how this measure would work in relation to orphan medicinal products and ATMPs.

Rather, the Rapporteur proposes to place an obligation on marketing authorisation holders to submit in every Member State, which requested them to do so, an application for pricing and reimbursement. In case of non-compliance with the obligation, a proportional financial penalty shall be applied by affected Member States. This can promote access to medicinal products across Europe, while ensure predictability in the expectations, as well as in the possible penalties, of marketing authorisation holders. Marketing authorisation holders of orphan medicinal products and ATMPs shall be subject to an adapted obligation, and in special cases the European Commission may exempt specific medicinal products. To further the processes surrounding the obligation, the European Commission shall set up an “EU Access to Medicines Notification System”.

Environmental Health

The Rapporteur welcomes the initiative of the European Commission to strengthen measures related to the environmental impact of medicines, and, by extension, the impact on human health of negative environmental impacts. However, these should be proportionate and not unjustly have a negative effect on patients.

Notably, the Rapporteur finds that in case of serious risks to the environment a marketing authorisation may be suspended or varied, but should only be revoked in cases where those risks clearly outweigh the loss of positive therapeutic effect of the medicine. The Rapporteur also asks the Commission to ensure that the proper guidelines for conducting environmental risk assessments for antimicrobials other than antibiotics are in place before obligations in this regard shall apply. When specifying technical details for the environmental risk assessments, all relevant stakeholders shall be consulted. As regards medicines for which a prescription is needed, the Rapporteur wishes to ensure continued patient access to antimicrobials not for systemic use.

The Rapporteur suggests to place extended obligations on the Member States with regard to the appropriate collection and management of unused or expired medicines. In this regard, Member States are asked to draw up national plans, including measures designed to inform the public and healthcare professionals about environmental risks in regard to incorrect disposal of medicines and increase its rate of correct disposal of medicines.

Patient-centred Information

The Rapporteur places emphasis on the importance of properly ensuring accurate information to patients about the medicines they consume. The first objective of package leaflets shall be to meet the needs of patients. Whether the leaflet is in electronic or in paper format, its content must be legible, clear and easy to use. The Rapporteur proposes that the package leaflet shall contain a 'key information section' to support this objective.

The addition by the European Commission of electronic information can, in this regard, benefit some patients. However, where no other position has been taken, the information should be available in the form of both paper leaflets and electronic product information. The decision to make information available only electronically shall lay with each Member State, and in this case, patients shall be made aware of their right to a printed copy. However, where the medicinal product is not intended to be delivered directly to, and administered by, the patient the Commission may take the decision to make only the electronic product information mandatory.

Awareness cards shall be available in paper format, or in both paper format and electronically, to support that this information is duly received by patients. The Rapporteur supports the proposal of the European Commission that Member States may make exemptions to the language requirements of labelling, however, patients should, in this case, still be able to request a copy in the official language of their Member State.

**ANNEX: LIST OF ENTITIES OR PERSONS
FROM WHOM THE RAPPOREUR HAS RECEIVED INPUT**

The following list is drawn up on a purely voluntary basis under the exclusive responsibility of the rapporteur. The rapporteur has received input from the following entities or persons in the preparation of the draft report:

Entity and/or person
2K/DENMARK
Abbvie
Advanced Accelerator Applications
Association of the European Self-Care Industry (AESGP)
Affordable Medicines Europe
Alexion
Alliance for Regenerative Medicines (ARM)
American Chamber of Commerce to the European Union
Amgen
Astellas Pharma
AstraZeneca
BioMarin
Bristol Myers Squibb
Boehringer Ingelheim
Childhood Cancer International Europe (CCI Europe)
Confederation of Danish Industry (DI)
Deutsche Stiftung Weltbevölkerung (DSW)
European Association of E-Pharmacies (EAEP)
Edwards Lifesciences
European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
European Federation of National Associations of Water Services (EurEau)
European Federation of Pharmaceutical Industries and Associations (EFPIA)
European Healthcare Distribution Association (GIRP)
EuropaBio - The European Association for Bioindustries
European Patients' Forum (EPF)
European Society for Paediatric Oncology (SIOP Europe)
German Medicines Manufacturers' Association (BAH)
Gilead Sciences
GRAKOM
GlaxoSmithKline Pharmaceuticals (GSK)
Intergraf
International Association of Mutual Benefit Societies (AIM)
International Diabetes Federation (IDF)
Johnson & Johnson
Medical Leaflets = Patient Safety (MLPS)
Medicines for Europe
MSD Europe
Novartis

Novo Nordisk
Novo Nordisk Foundation
Pfizer
PTC Therapeutics
Regulatory Institute
Roche
Sanofi
Servier
Standing Committee of European Doctors (CPME)
Stibo Complete
Takeda
Vaccines Europe
Vertex Pharmaceuticals
Viatrix